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APPLICATION NUMBER: *60/479,320*
FILING DATE: *June 18, 2003*

PCT/AU04/796

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06-19-03 60479320 US 06/18/03

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This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EV 225384324 US

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☐ *Additional inventors are being named on the* 0 *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

METHOD AND APPARATUS FOR MONITORING BARIATRIC PARAMETERS AND SLEEP DISORDERED BREATHING

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages*	5	☐ CD(s), Number	
☑ Drawing(s) *Number of Sheets*	1	☑ Other (specify)	return itemized postcard
☐ Application Data Sheet. See 37 CFR 1.76			

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☐	Applicant claims small entity status. See 37 CFR 1.27.	FILING FEE AMOUNT ($)
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☐ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE [signature]

Date 6/18/2003

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Docket Number: 3869/035

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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METHOD & APPARATUS FOR MONTIORING BARIATRIC PARAMETERS & SLEEP DISORDERED BREATHING

There is a clinically recognised relationship between a subject's body mass and the likelihood of the subject suffering from a form of sleep disordered breathing (SDB) such as obstructive sleep apnea (OSA). There is a clinically recognised measure of relative body mass know as the body mass index (BMI). The greater the BMI the more likely the subject is to suffer from OSA. Accordingly an OSA sufferer may be advised to reduce their BMI as a step in the management of their OSA condition. Many options are available to a subject wishing to reduce their BMI eg strict diet control and vigorous exercise. Strict diet control can be achieved through the subject voluntarily limiting their intake of the amount of food, especially food associated with an increase in BMI such as fats. As an aid to controlling food intake a subject may undergo bariatric surgery where their stomach is stapled so as to reduce the amount of food that may be digested in a given period.

For a subject undergoing a program to modify their BMI it can be useful for the clinician to monitor the subject's BMI changes over a period. Typically the BMI is calculated by reference to body weight. Accordingly the tracking of BMI is achieved by taking measurements of a subject's weight over a period, typically no more frequently than daily.

If the subject is a suspected or actual SDB sufferer then it is clinically useful to track their BMI over a period during which the subject is undergoing treatment for the SDB. For example the subject may be undergoing nasal CPAP treatment for OSA during the relevant period.

The present invention allows for the recording and collation of data relevant to the management of a subject participating in a BMI modification program. The invention is particularly useful where the subject is also participating in a SDB management program. In this context the patient would undergo their usual nightly nasal CPAP or non-invasive positive pressure ventilation (NIPPV) treatment while their weight measurements are recorded and processed in accordance with present invention.

The present invention provides a convenient method of presenting the subject and their clinician with both the subject's BMI measurements and their nasal CPAP therapeutic pressure changes.

The present invention has the advantage of encouraging the subject to actively participate in the management of their health conditions and thereby promote better compliance with associated treatment.

Alternatively the invention may be used as a monitoring tool in the context of a program where the subject is undergoing SDB management by a method other than nasal CPAP or NIPPV. In this alternative context the subject would undergo an infrequent nasal CPAP or NIPPV treatment session so as to obtain the data relevant to determining the progress of their SDB condition. This information would then be used to determine the effectiveness of the method other than nasal CPAP or NIPPV being used to manage their SDB.

As another alternative the present invention may be practiced where the subject does not receive nasal CPAP or NIPPV treatment but rather their breathing (especially their breathing during sleep) is monitored but not treated. For example the invention may be practiced in the context of a system for measuring a subject's breathing flow limitation episodes and the calculation of the subject's Apnea Hypopnea Index (AHI) or Apnea Index (AI). An example of a system that is capable of gathering and processing breathing data is the Embletta Portable Diagnostic System from Flaga hg .

The present invention also provides a method and apparatus for determining the relative condition of a patient during a period of modification of their BMI.

Nasal CPAP systems, NIPPV systems and SDB screening apparatus by ResMed Limited are particularly well suited for use with the present invention eg AutoSet Spirit automatically titrating nasal CPAP system by ResMed Limited and the US Patents 5,704,345 & 6,363,933 the contents of which are hereby incorporated by reference in their entirety and the AutoSet CS adaptive servo ventilator by ResMed Limited and US Patents 6,532,959, 6,484,719 and 6,532,957 the contents of which are hereby incorporated by reference in their entirety. These automatically titrating systems are particularly useful for use with the invention for they allow for the nasal CPAP or NIPPV treatment pressure to vary during the course of a treatment session (eg through the night) and from session to session (i.e. from night to night). They also have a great capacity to collect, store and display data regarding the subject's breathing and the treatment pressures they deliver in response to the subject's condition.

Set out below is an example of an embodiment of the invention. This example describes the incorporation of the invention into the automatically titrating nasal CPAP system AutoSet Spirit by ResMed Limited for use by a subject undergoing nasal CPPA treatment for OSA. The clinical pathway adopted for the subject requires the subject to record their weight on a daily basis. The AutoSet Spirit is modified so as to include the capacity to receive and record in memory the subject's height and weight. There is sufficient memory capacity to record weight on a number of occasions, preferably on a daily or weekly basis over a suitable period i.e. a period of thirty days. The system will tag the weight data with day and preferably the time that it is entered. In this embodiment the device display screen prompts the subject to enter the weight data by way of the device control buttons. In an alternative embodiment an electronic scales system could be hard wired or remotely communicating with the device so as to allow for automatic transfer of the weight data.

Using the height and weight data the system will calculate the subject's BMI in accordance with the formula:

Body Mass Index can be calculated using pounds and inches with this equation

$$BMI = \left(\frac{\text{Weight in Pounds}}{(\text{Height in inches}) \times (\text{Height in inches})} \right) \times 703$$

For example, a person who weighs 220 pounds and is 6 feet 3 inches tall has a BMI of 27.5.

$$\left(\frac{220 \text{ lbs.}}{(75 \text{ inches}) \times (75 \text{ inches})} \right) \times 703 = 27.5$$

The reference to this formula for BMI calculation is the web site:
http://www.cdc.gov/nccdphp/dnpa/bmi/bmi-adult-formula.htm

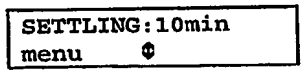
Because the system records the subject's height and the weight data is associated with the day that it is entered a BMI for each weight entry may be generated and identified with the day that the weight data was entered. Various data and BMI viewing modes may be programmed to suit the particular requirements of the clinical pathway adopted for the subject. For example in one mode the subject may be given access only to the height data and the weight data at the time it is entered while the clinician may have full access to all data entered. As a variant the subject may have access to the BMI for a particular day but no historic data. Alternatively the data and BMI viewing modes may only be accessed by the subject because the full data set may only be accessed by use of secret password.

The data may be displayed in any suitable form so as to suit the particular requirements of the clinical pathway adopted for the subject. An example of a data display is set out in Figure 1. Figure 1 shows an example computer screen shot of what may be displayed including the subject's weight, BMI, AHI & AI, usage (compliance) time and nasal CPAP treatment pressure delivered by the AutoSet Spirit nasal CPAP system for the identifed days.

The data may be accessed by direct interrogation of the device through use of its control buttons and data screen. Alternatively the data may be accessed through use of control modules, which can be directly connected to the device comms port. An example would be a cable connecting the device comms port with a computer running data acquisition and display software. In yet another way the data may be transmitted to a remote site by way of modem transmission or wireless transfer such as by way of pager technology where the modem or pager transceiver is connected to the device comms port.

An example of how the invention may be operated is now described.

When the AutoSet Spirit is powered on the WELCOME screen is displayed for 5 seconds followed by the SETTLING screen (if MODE = AUTOSET or RAMP if MODE=CPAP).



Pressing menu button takes the user to the data screens.

- The **WEIGHT** screen allows the user to enter their weight for **today** (ie the day of entry) in pounds. Once the subject has entered a weight for a day, the following and all subsequent days will start with the last entered value which the user can then modify in steps of +/- 1 pound using the arrows. This feature allows for convenient data entry as it may be expected that while a subject's weight will vary over time it will vary by no more than few pounds between consecutive days.
- The **REVIEW WEIGHT** menu allows the subject to examine the weight entered for the last 30 days. If a weight was not entered on a day it will show "**N/A**" for Not Available.
- The screens shown below on the right are the screens the subject sees when they press the **change** or **enter** keys.
- The **HEIGHT** screen allows the user to enter their **HEIGHT** in inches.
- The **BMI** screen then displays Body Mass Index = (WEIGHT/(HEIGHT * HEIGHT)) * 703 where the **WEIGHT** is the current weight entered. The label below **BMI** is one of "**Normal, Overweight, Obese,** or **Extreme**" based on the classification of BMI in The Evidence Report.

WEIGHT (lbs):300 change ↓ exit
REVIEW WEIGHT enter ↕ exit
HEIGHT (in):70 change ↕ exit
BMI: 43.0 Extreme ↕ exit
USED: 1234hrs 50/70days exit
SW:SX1160211 ↑ exit

WEIGHT (lbs):300 apply ↕ exit
WEIGHT (lbs):300 10Jul03 ↕ exit
HEIGHT (in):70 apply ↕ exit

- Range of **WEIGHT** is 90 to 450 pounds. Default value is 325 pounds.
- Range of **HEIGHT** is 40 to 80 inches. Default value is 68 inches.

The classification of BMI values against a BMI range is adapted from "Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults", The Evidence Report (reference: The National Heart, Lung, and Blood Institute.http://www.nhlbi.nih.gov/guidelines/obesity/bmi_tbl.htm).

Classification	BMI Range
Normal	19-24
Overweight	25-29
Obese	30-39
Extreme Obesity	40-54

[redacted]

There are other ways that the data menu structure may be configured so as to address particular clinical pathway requirements eg displaying the **BMI** value on each of **WEIGHT** review screen. There may be included a message system that would provide messages of encouragement, suggestions for improvement or warnings depending on how the subject's condition was progressing.

1.1 ResScan display of Weight Values

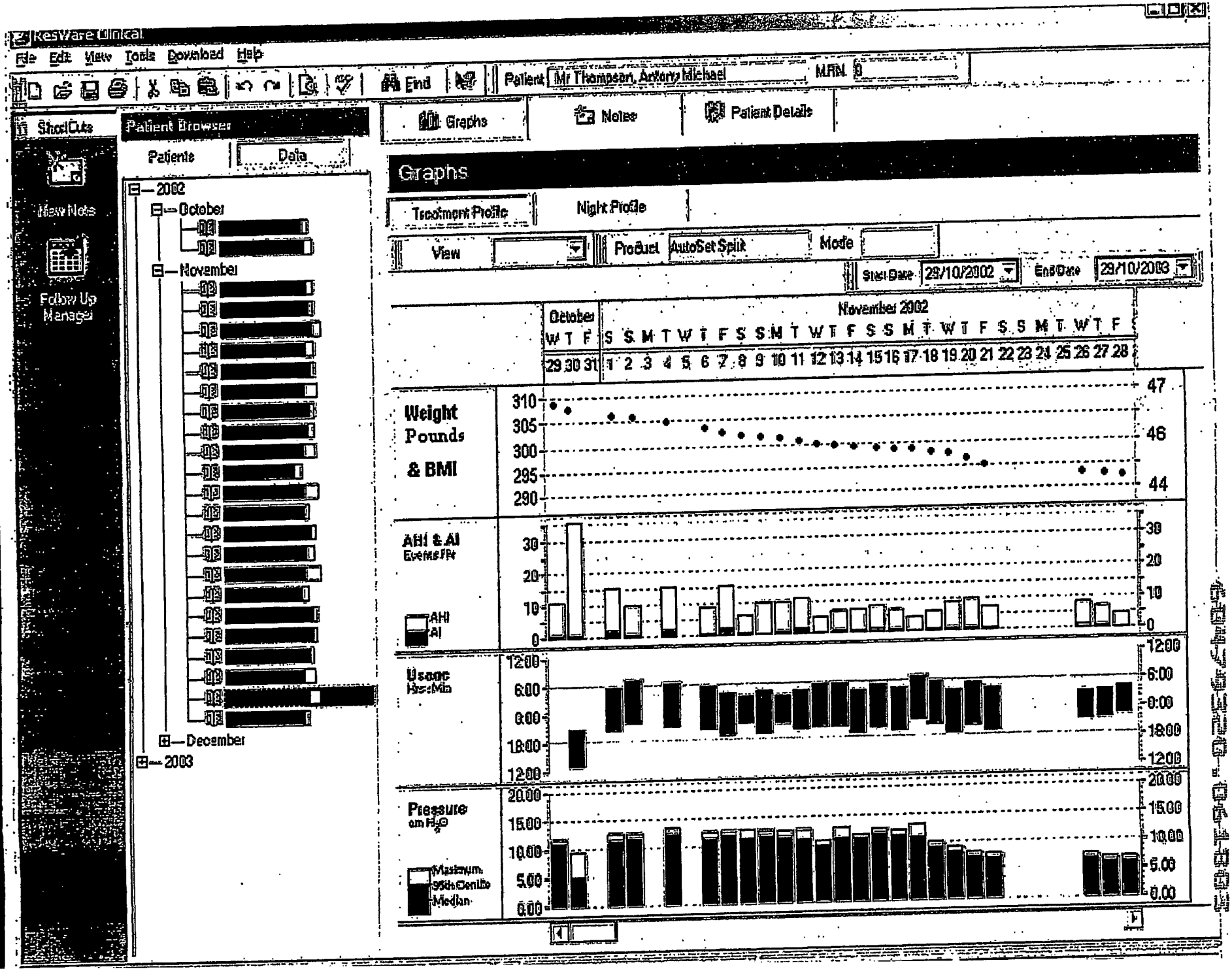
A display picture has been prepared of a ResScan windows application and appears as Figure 1. ResScan is a ResMed Limited proprietary software which is distributed to clinicians so as to allow access to the data in AutoSet Spirit devices. The Figure 1 display picture (screen shot) displays the **WEIGHT** value from the modified AutoSet Spirit on a daily basis. This can be displayed against other recorded values such as **PRESSURE, USAGE** and **AHI** & **AI**. The picture display provides readily accessible information about the subject's condition and in this example displays the expected trend of the **PRESSURE** (i.e. nasal CPAP pressure) trending down as the subject's weight reduced. The display of this information in this manner serves to allow for the convenient recognition of trends and the possible correlations between physiological phenomena. When the data is considered in the context of the subject's whole clinical management regime it is possible to readily determine the effectiveness or otherwise of BMI modifying treatment and OSA management.

1.2 BMI Display Value

Some sample values for BMI are contained in the table below (as a quick check)

HEIGHT (inches)	**WEIGHT (pounds)**	**BMI**
68	300	45.6
70	285	40.9
70	300	43.0
70	320	45.9
72	300	40.7

[redacted]


ResMed Ltd
File Edit View Tools Download Help
Find
Patient Mr Thompson, Antony Michael
MRN 0
ShortCuts
New Note
Follow Up Manager
Patient Browser
Patients
Data
2002
October
November
December
2003
Graphs
Notes
Patient Details
Graphs
Treatment Profile
Night Profile
View
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